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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,967

03/22/2004

Dennis Collieran

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08/21/2006

EXAMINER

REIMERS, ANNETTE R

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ART UNIT

PAPER NUMBER

3733

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/805,967

Applicant(s)

COLLERAN ET AL.

Examiner

Annette R. Reimers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-30 and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 14, 21, 29 and 30, the screw form regarding the rearward-facing thread is unclear. Applicant states "a rearward-facing thread surface having a substantially straight sloped portion and at least two non-contiguous curve portions, such that a point on the rearward-facing thread surface at a root of the thread surface is farther from the forward end than a point on the rearward-facing thread surface at a crest of the thread surface when measured along a line parallel to the longitudinal axis." However, based on Figure 4, i.e., the figure cited by applicant in support of the amendments to the claims, the rearward-facing thread surface has a substantially straight sloped portion and at least two non-contiguous curve portions, such that a point on the rearward-facing thread surface at a root of the thread surface appears to be closer to (not farther from) the forward end than a point on the rearward-facing thread surface at a crest of the thread surface when measured along a line parallel to the longitudinal axis. Appropriate correction is required.

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In claims 7, 30, 35, 36 and 37, the screw form regarding the forward-facing thread is unclear. Applicant states "a forward-facing thread surface having a substantially straight sloped portion and at least two non-contiguous curve portions, such that a point on the forward-facing thread surface at a root of the forward facing thread surface is closer to the forward end than a point on the forward-facing thread surface at a crest of the forward facing thread surface when measured along a line parallel to the longitudinal axis." However, based on Figure 4, i.e., the figure cited by applicant in support of the amendments to the claims, the forward-facing thread surface has a substantially straight sloped portion and at least two non-contiguous curve portions, such that a point on the forward-facing thread surface at a root of the forward facing thread surface appears to be farther from (not closer to) the forward end than a point on the forward-facing thread surface at a crest of the forward facing thread surface when measured along a line parallel to the longitudinal axis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 10-30 and 35-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson (US Patent Number 6,726,689).

Jackson discloses various embodiments of a medical implant device, 8, comprising a receiver member, 10, including a plurality of wall sections defining a longitudinal bore, wherein the wall sections have an inner threaded portion and a closure member, (see figure 5) including a rearward end, a forward end, a substantially cylindrical body having a longitudinal axis, and an outer threaded portion for threaded engagement with the inner threaded portion of the receiver member, wherein the outer threaded portion includes a screw form for a given cross-section of the thread through a plane which includes the longitudinal axis, the screw form comprising: a rearward-facing thread surface having a substantially straight sloped portion and at least two non-contiguous curve portions, such that a point on the rearward-facing thread surface at a root of the thread surface is farther from the forward end than a point on the rearward-facing thread surface at a crest of the thread surface when measured along a line parallel to the longitudinal axis (see figure 5). Furthermore, Jackson discloses that the surfaces may be angled so as to slope downward or upward as the surface extends radially outward (see figure 5 and column 12, lines 48-51).

In addition, the screw form further comprises a forward-facing thread surface having a substantially straight sloped portion and at least two non-contiguous curve portions, such that a point on the forward-facing thread surface at a root of the forward facing thread surface is closer to the forward end than a point on the forward-facing

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thread surface at a crest of the forward facing thread surface when measured along a line parallel to the longitudinal axis (see figure 5).

The receiver member also includes a transverse channel substantially perpendicular to the bore and is a part of a bone fixation device (see figure 3). The bone fixation device is a bone screw or hook (see figure 3 and column 3, line 61). The closure member is capable of being a setscrew (see column 10, lines 33-35). The outer threaded portion defines a dovetail when viewed in section (see figure 11).

The outer threaded portion is configured as a helical spiral about the body, and wherein the thickness of the outer threaded portion at its crest varies along the helical spiral (see figures 4-10). In addition, the outer threaded portion is configured as a helical spiral about the body, wherein the thickness of the outer threaded portion at its root varies along the helical spiral (see figures 4-10). Furthermore, the outer threaded portion is configured as a helical spiral about the body, wherein a peak thickness of the outer threaded portion occurs crestward of the outer threaded portion's root, and wherein the thickness of the peak thickness varies along the helical spiral (see figures 4-10). Moreover, the thickness of the peak thickness is thicker at a rearward portion of the helical spiral than at a forward portion of the helical spiral relative to the direction of advancement of the closure member when being inserted into the receiving member (see figures 4-10).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Jackson, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152

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USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Patent Number 6,726,689).

Jackson discloses the claimed invention except for an angle measured between the substantially straight sloped portion of the forward-facing thread surface and the substantially straight sloped portion of the rearward-facing thread surface being between about 2 degrees and 40 degrees, and the measured angle being about 15 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Jackson with an angle measured between the substantially straight sloped portion of the forward-facing thread surface and the substantially straight sloped portion of the rearward-facing thread surface being

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between about 2 degrees and 40 degrees and the measured angle being about 15 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments do not comply with 37 CFR 1.111(c), because they do not clearly point out the patentable novelty, which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In response to applicant's argument regarding the Jackson patent, it is noted that the argument merely states what limitations the claims require by repeating, the claim limitations in the argument and then stating the conclusion that the prior art does not disclose those limitations. Rule 37 CFR 1.111(b) requires that applicant **MUST** "distinctly and specifically point out errors" in the examiner's action. In addition, arguments or conclusions of the attorney cannot take the place of evidence. *In re Cole*, 51 CCPA 919, 326 F.2d 769, 140 USPQ 230 (1964); *In re Schulze*, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); *Meitzner v. Mindick*, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

Furthermore, the device of Jackson does disclose a closure member including a rearward end, a forward end, a substantially cylindrical body having a longitudinal axis, and an outer threaded portion for threaded engagement with the inner threaded portion of the receiver member, wherein the outer threaded portion includes a screw form for a

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given cross-section of the thread through a plane which includes the longitudinal axis, the screw form comprising: a rearward-facing thread surface having a substantially straight sloped portion and at least two non-contiguous curve portions, such that a point on the rearward-facing thread surface at a root of the thread surface is farther from the forward end than a point on the rearward-facing thread surface at a crest of the thread surface when measured along a line parallel to the longitudinal axis (see figure 5). In addition, the screw form further comprises a forward-facing thread surface having a substantially straight sloped portion and at least two non-contiguous curve portions, such that a point on the forward-facing thread surface at a root of the forward facing thread surface is closer to the forward end than a point on the forward-facing thread surface at a crest of the forward facing thread surface when measured along a line parallel to the longitudinal axis (see figure 5).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER